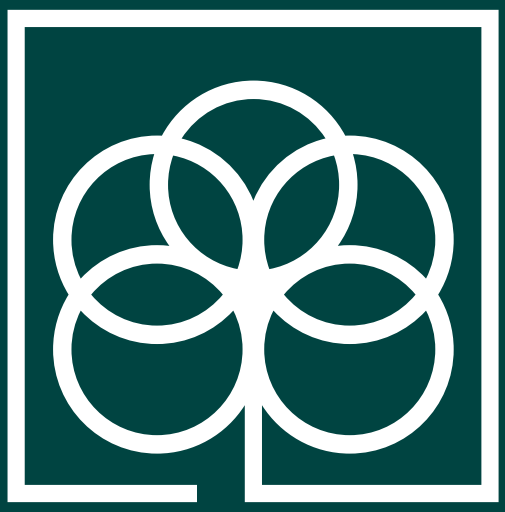

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Regulatory Briefing

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New Park Court

REGULATORY BRIEFING

by Danielle Gilmour

Regulating Healthcare at Events

Danielle Gilmour represented a Core Participant in the Manchester Arena Inquiry.
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Regulating healthcare at events

"If a lack of regulation gives rise to a risk of injury and death, then that is a state of affairs that cries out for effective regulation."

Paul Greaney KC, Counsel to Manchester Arena Inquiry
7 June 2023

On 22 May 2017 at 22:31 a devastating bomb attack was carried out in the City Room at the Manchester Arena.

The explosion killed 22 people. Some died instantly, others did not. Many more people were injured.

The injured and, in their final moments, some of the deceased, received treatment from a variety of people and organisations whilst waiting for the emergency services to arrive and attend to them.

Emergency Treatment UK (ETUK), an event healthcare provider had been contracted by those running the venue for the event that night. Having acknowledged the courage shown by those who entered the City Room, the Chairman of the Manchester Arena Inquiry ('the Inquiry'), Sir John Saunders concluded that ETUK as an organisation was ill-prepared for a major incident, that it's staff underqualified and that, overall, the healthcare provided it was inadequate.

The quality of healthcare and treatment provided in the gap between an incident, the arrival of the emergency services and treatment being administered was examined in detail by the Inquiry. That gap, which was dubbed 'the care gap', is widely accepted to be inevitable in any major incident involving the public and the only thing that will vary is the length.

In January 2022 the Manchester Arena Inquiry heard evidence that the care gap is often 'filled' by uninjured members of the public, who are present assisting their family, friends and fellow citizens; and at events where there is a first aid service or other temporary on-site healthcare provision, it is also expected to be provided by them.

However, despite the critical role that those providing those healthcare services are expected to – and do - play at such events, the provision of healthcare at events is an entirely unregulated sector, other than in relation to private ambulances transporting casualties away from the scene.

The Care Quality Commission (CQC) is the statutory regulator for health and social care in England. It has regulatory oversight for providers of regulated activities; that is activities that are provided within the health and social care sector which are required to be regulated. It was created by the Health and Social Care Act 2008 and was given a range of regulatory oversight and enforcement powers. Section 10 of the Health and Social Care Act 2008 requires those who provide regulated activity to be registered with the CQC. Where that requirement is breached a criminal offence is committed.

In April 2015, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ('the Regulations') came into force and provided, amongst other things, (i) fundamental standards for providers to meet, and (ii) extended powers to prosecute for breaches of certain of those fundamental standards.

The types of activity that fall within the scope of CQC regulation - the 'regulated activities' - are provided within Schedule 1 of the Regulations. That Schedule also provides for certain exemptions to the scope. The provision of the treatment of disease, disorder or injury (TDDI) is one of the prescribed regulated activities. Regulation 12 of the Regulations provides that all care and treatment must be provided in a safe way.

However, by virtue of paragraph 4 (3) (g) of Schedule 1 of the Regulations, where that treatment is healthcare which is provided at certain events (i.e. sporting or cultural events), it falls outside of the CQC's scope and is therefore exempt from CQC regulation and oversight.

The CQC's perspective

The CQC has received several reports of unsafe care, abuse and death relating to this sector and has expressed its concern and desire to regulate the sector.

In December 2019 the CQC wrote to the Department of Health and Social Care (DHSC) with proposed topics for review within the Regulations. Of those proposals, the regulation of the provision of healthcare at events was the CQC's top priority. This was nine months before the Inquiry began to hear evidence, and more than 12 months before it began to hear evidence about the emergency response.

In evidence provided to the Inquiry, witnesses from the CQC - Dr Edward Baker (in January 2022) and Joyce Frederick (June 2023) - confirmed that this remains the CQC's position. The CQC also agrees with the Chairman's recommendations and believes that it is the body that should be responsible for regulation in this sector. Those who practice in the field of healthcare regulation will know that the CQC has the experience and expertise to do so. More importantly, it has the experience and the expertise to do so with the required urgency.

What next then, for the provision of healthcare at events?

On 3 November 2022, Volume 2 of Sir John Saunders' report on the findings from the Manchester Arena Inquiry was laid before Parliament. The following recommendations were made:

> ***Recommendation 132****: The Department of Health and Social Care should establish the standard for the level of healthcare services required at events. Consideration should be given to putting that standard on a statutory footing.*
>
> ***Recommendation 133****: That standard needs to be regulated and enforced. The Care Quality Commission is the appropriate body to provide regulation and enforcement. The Department of Health and Social Care should give urgent consideration to making the necessary changes in the law so as to enable the CQC to become the regulator for this sector.*

At present, what is required to bring the provision of healthcare at events within the scope of CQC regulation and oversight, is the *removal* of sub-paragraph (g) from paragraph 4 of Schedule 1. A single amendment, in the form of a deletion.

However, it does not necessarily follow that just because the legislation may be easily amended that means that change is straightforward.

The DHSC's perspective

Volume 2 of the Chairman's Report also included the following recommendations:

> ***Recommendation 134****: The Department of Health and Social Care together with the Care Quality Commission should consider what the consequences of breaching the appropriate standard should be. That should include consideration of whether the sanction should be criminal in nature.*
>
> ***Recommendation 135****: The Department of Health and Social Care and the Care Quality Commission should consider introducing guidelines to ensure that all event healthcare staff who work at events are trained in first responder interventions.*

In evidence to the Inquiry on the 7 June 2023, Emma Reed from the DHSC gave assurance that the government recognises that there are no standards in place for this sector and that the DHSC accepts R132 and R133. It was also confirmed that the DHSC have been working with the Home Office because the sector and therefore R132 is also impacted by the requirements of the so-called 'Protect Duty', a Draft Bill driven by a member of the bereaved families which featured in the Inquiry's recommendations and which is presently making its way through Parliament. It is expected that this Draft Bill will be enacted into law, and will be the subject of a separate post.

However, before committing to setting out *how* the DHSC will proceed with those Recommendations - and before accepting R134 and R135 – Ms Reed explained that the DHSC wants to review the Regulations. Until that review is completed, the DHSC is not prepared to commit to amending the Regulations to bring healthcare at events within the scope of the CQC.

This is a response requiring examination.

On one hand, the government recognises that the sector needs to have established standards for the events healthcare sector. It accepted in evidence that the sector is unregulated and that that lack of regulation has created a risk of unsafe care, injury, abuse and death. It accepts Recommendations 132 and 133. It did not dispute that Article 2 is engaged and confirmed that the DHSC has been collaborating with the Home Office on the healthcare standards issues within the draft Protect Duty bill.

But on the other hand, six years after the event, three and a half years after the CQC first sent it's proposals, 17 months after the CQC first gave evidence on this issue, and 7 months after the Chairman's report was laid before Parliament, the DHSC cannot provide an indication of how it is going to implement change in this area, reduce the ongoing risks and protect the public. It is also unclear what the DHSC perceives the complicating factors to be. That said, the DHSC did point to the unprecedented impact of the COVID 19 pandemic as an explanation for why its work in this area, which began in 2019, has not been completed.

Pathway to change

One of the topics that those of us who practice in the field of regulatory compliance will be mindful of is what standards will be imposed and how healthcare providers – both extant and newly incorporated – will meet those standards. That would normally be an issue demanding a significant amount of time in the preliminary stages of introducing regulatory oversight, and hopefully incorporate the views of those operating within the sector affected by the changes. It would also be an area upon which clients would require advice, both prior to implementation and on an ongoing basis, to ensure their interests are protected in terms of compliance and liability – whether civil, criminal or otherwise – which in the absence of any indication from those responsible for implementing the standards such as we have now, is a difficult task.

However, if the approach taken by the DHSC is the simple step of removing those 35 words from Schedule 1, rendering the provision of the TDDI at events subject to the same regulation by the CQC as TDDI in environments already in scope, it is difficult to see a situation in which the fundamental standards (i.e. the Regulations) could or would differ.

It is likely that the risk addressed by Regulation 12 will remain a particularly important issue, importing standards and guidance for the provision of 'safe care and treatment'. Other areas that will likely be of concern will be those addressed by Regulation 13 (safeguarding from abuse and improper treatment) and Regulation 15 (ensuring safe and fit for purpose premises and equipment). These are not only areas which most healthcare lawyers are familiar with, but they are also topics which would easily translate from traditional 'permanent' care settings into newer 'temporary' settings such as sporting or cultural event venues.

If that is the case then advisors to current providers of regulated activity and the CQC are well positioned to advise on compliance issues in this sector as well. The fundamental standards are objective standards but are applied in a way subject to the environment and with regard to national guidance that is widely available and accessible. Experience and knowledge of how the CQC operates as a civil and criminal enforcer as well as a regulator will also be of significant value to providers and clients who find themselves thrust into a new area of regulation, as new areas of regulation intended to have teeth can be difficult to navigate in the early stages of investigations or other proceedings.

One way of reading ahead in the regulatory landscape, whilst waiting for the DHSC to publish the scope of their review in this sector, will be to have one eye on the movement of the Protect Duty and the standards and guidance associated with healthcare provision in that. The evidence to the Inquiry of the director of Protect and Prepare, CBRNE, and Science and Technology in Homeland Security Group in the Home Office,which was given after the CQC and DHSC witnesses had been called, alluded to a desire to synchronise with the DHSC on the task of healthcare provisions within the Protect bill. There is no guarantee that any healthcare provision standards associated with the Protect Duty will mirror or be identical to any implemented through a separate regulator, but it is not difficult to see the problems that would be stored up within the sector if separate or competing standards are applied by a different piece of legislation and/or a regulator.